GP 1632

CASE 4-30583A

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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IN RE APPLICATION OF

Art Unit: 1632

TECH CENTER 1600/2900

AMLOT ET AL.

Examiner: Ewoldt, Gerald R.

APPLICATION NO: 09/770,002

FILED: JANUARY 25, 2001

FOR: USE OF CD25 BINDING MOLECULES IN THE TREATMENT OF

RHEUMATOID ARTHRITIS OR SKIN DISEASES

Assistant Commissioner for Patents Washington, D.C. 20231

## RESPONSE TO RESTRICTION REQUIREMENT

Sir:

This is in response to the Office Action mailed March 20, 2002.

The Examiner has indicated that the claimed subject matter is drawn to two distinct inventions and has required restriction to one of the following inventions, Group I: Claims 1-3 and 9-11, drawn to a CD25 binding molecule and a pharmaceutical composition comprising the CD25 molecule; and to Group II: Claims 4-6 and 8, drawn to a method for the treatment of rheumatoid arthritis or skin diseases. Applicants provisionally elect, with traverse, to prosecute the invention of Group II: Claims 4-6 and 8.

35 U.S.C.§ 121 maintains that for a proper requirement for restriction, the dual criteria of the statute must be met, that is, the application must contain two or more inventions which are both (1) "independent" and (2) "distinct" from one another. According to the U.S. Patent and Trademark Office's own definition, "independent" means "there is no disclosed relationship between the two or more subjects disclosed, that is they are unconnected in design, operation or effect..." [Emphasis added]. (Section 802.01 of the Manual of Patent Examining Procedure). The specification of the present application discloses a relationship and connection between the claims of Group II and Group I. In particular, the CD25 binding molecule defined in Group I is required in the method of Group II, i.e., method for the treatment of rheumatoid arthritis or skin diseases. Thus, the claims of Group II are related and connected to the claims of Group I. Accordingly, the requirement for

restriction and election is unwarranted under 35 U.S.C. §121 which, in order to authorize restriction, requires that the application claim "two or more independent and distinct inventions" [Emphasis added].

As a second ground for traversal, Applicants submit that the Examiner has failed to show that there would be a "serious burden" upon the Patent and Trademark Office to examine all of the pending claims. In this regard, MPEP §803, second paragraph, states:

"There must be a serious burden on the examiner if restriction is required."

It is respectfully submitted that since all of the claims in Groups I and II require the identical CD25 binding molecule, that a search and examination of Group I would substantially overlap with a search and examination of Group II and therefore would not impose a "serious burden" on the Examiner. In view of the above, withdrawal of the Restriction Requirement is respectfully requested. Applicants retain the right to petition from the Restriction Requirement under 37 C.F.R.§1.144.

Early and favorable action are respectfully requested.

Respectfully submitted,

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Date: April 16, 2002

Susan Hess

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